

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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THEDA JACKSON-MAU, on behalf of
herself and all others similarly situated

Plaintiff,

-against-

WALGREEN CO. and
INTERNATIONAL VITAMIN
CORPORATION,

Defendants.
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MEMORANDUM AND ORDER

Case No. 1: 18-cv-4868 (FB)(VMS)

Appearances:

For the Plaintiff:

WOLK POPPER LLP
MATTHEW INSLEY-PRUITT, ESQ.
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For the Defendant:

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BLOCK, Senior District Judge:

Plaintiff Theda Jackson-Mau brings this action against International Vitamin Corporation (“IVC”) for violations of New York General Business Law §349 related to its manufacturing of glucosamine sulfate. The defendant moves to dismiss the state claim against it based on federal preemption under Federal Rules of Civil Procedure 12(b)(6) and the claim for injunctive relief under 12(b)(1). For the following reasons, the defendant’s motion is granted in part and denied in part.

I.

“A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it,” *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000), such as for lack of standing to seek injunctive relief. *Pungitore v. Barbera*, 506 F. App’x 40, 41 (2d Cir. 2012). Plaintiff bears the burden of establishing standing. *All. for Open Soc’y Int’l, Inc. v. U.S. Agency for Int’l Dev.*, 651 F.3d 218, 227–28 (2d Cir. 2011), *aff’d sub nom. Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 133 S. Ct. 2321, 186 L. Ed. 2d 398 (2013) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)).

For dismissal under 12(b)(6), the Court must take as true all the allegations of the complaint and must draw all inferences in plaintiff’s favor. *See Weixel v. Board of Educ.*, 287 F.3d 138, 145 (2d Cir. 2002). A complaint “does not need detailed factual allegations,” but “a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Id.* at 555. Federal preemption is an affirmative defense; therefore, the defendant bears the burden of proof. *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n. 2 (2011).

II.

Plaintiff's relevant testing allegations are as follows: (1) she purchased a bottle labeled Glucosamine Sulfate at Walgreens, (2) she brought the bottle to her counsel, who had the pills professionally analyzed, (3) the lab tests uncovered "that there was *no* Glucosamine Sulfate in the pills that were tested" despite the bottle stating the pills contained Glucosamine Sulfate, and (4) "[i]t is implausible to consider that [the lab test result] is the result of simple manufacturing variance." Amended Compl. ¶¶22-24 (emphasis in original).

IVC contends that Plaintiff's claim must be dismissed because it is preempted by federal regulation. IVC argues that this Court's decision in Walgreen's motion to dismiss (the "Walgreen's decision") only held that "Plaintiff's complaint should not be dismissed for failure to plead compliance with the federal testing requirements set out in 21 C.F.R. §101.9(g)," in other words, that Plaintiff's omission was not sufficient for dismissal. IVC now asks the Court to address two variations of the preemption argument: 1) whether Plaintiff must affirmatively plead compliance with the federal testing requirement to avoid dismissal, and 2) whether the complaint "affirmatively pleads facts establishing an affirmative defense-preemption of her claim." The Court's answer to both questions is no.

a. Plaintiff is not required to plead compliance with federal testing requirements to state a claim

IVC argues that Plaintiff must affirmatively plead compliance with federal testing requirements to state a claim for mislabeling and avoid dismissal due to preemption. However, the only new case IVC cites since the Walgreen's decision that is on point is not controlling. *See Melendez v. ONE Brands, LLC*, 2020 WL 1283793 (E.D.N.Y. Mar. 16, 2020). Instead IVC cites *Lexmark* to assert what amounts to a legal truism: if a plaintiff does not allege the elements of a claim, the claim must be dismissed. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014). No one disputes that. But the district courts remain split on the issue,¹ and the Second Circuit still has not addressed whether affirmative pleading of compliance with federal testing requirements is required to survive a motion to dismiss.

¹ Compare cases that required dismissal where plaintiff did not plead compliance with the FDA protocol, *Parker v. Wal-Mart Stores, Inc.*, 367 F.Supp.3d 979 (E.D. Mo. 2019); *Welk v. Nutraceutical Corp.*, 3:17-CV-02266-BEN-KSC, 2018 WL 3818033 (S.D. Cal. Aug. 10, 2018); *In re Whole Foods Mkt., Inc.*, 163 F.Supp.3d 385 (W.D. Tex. 2016); *Dougherty v. Source Nats., Inc.*, 148 F. Supp. 3d 831 (E.D. Mo. 2015); *Mee v. I A Nutrition, Inc.*, No. C-14-5006 MMC, 2015 WL 2251303 (N.D. Cal. May 13, 2015); *Baker v. NNW, LLC*, No. 15-00222-CV-W-GAF, 2015 WL 12843827 (W.D. Mo. July 8, 2015); *Bruaner v. MusclePharm Corp.*, No. 14-cv-8869-FMO, 2015 WL 4747941 (C.D. Cal. Aug. 11, 2015) with cases where pleading compliance was not required for court to infer defendant's liability. *Carrol v. S.C. Johnsons & Son, Inc.*, No. 17-CV-05828, 2018 WL 1695421 (N.D. Ill. Mar. 29, 2018); *Gubala v. CVS Pharmacy, Inc.*, No. 14-cv-9039, 2016 WL 1019794 (N.D. Ill. Mar. 15, 2016); *Gubala v. HBS Int'l Corp.*, No. 14-cv-9299, 2016 WL 2344583 (N.D. Ill. May 4, 2016); *Clay v. Cytosport, Inc.*, No. 15-cv-165 L(DHB), 2015 WL 5007884 (S.D. Cal. Aug. 19, 2015); *Smith v. Allmax Nutrition, Inc.*, No. 1:15-cv-00744-SAB, 2015 WL 9434768 (E.D. Cal. Dec. 23, 2015).

At the summary judgment stage, the Court may need to determine whether the federal requirements were used or whether Plaintiff's test was an appropriate substitute.² But at this juncture, viewing the allegations in the light most favorable to the plaintiff, the Court will assume that Plaintiff's testing is adequate.

b. Plaintiff did not plead Defendant's affirmative defense.

IVC argues that Plaintiff has established Defendant's affirmative defense of preemption by supporting her allegations with a testing method different than the federal requirement. IVC points to Eleventh and Ninth Circuit cases that were already considered in the Walgreen's decision to support its argument. In *Hi-Tech Pharmaceuticals, Inc. v. HBS International Corp.*, the claims were dismissed based on preemption, but they did not reach the issue of whether dismissal was warranted based on a failure to allege federally compliant testing nor did they even mention dismissal based on Plaintiff's pleading the use of a different test. 910 F.3d 1186 (11th Cir. 2018). In *Durnford v. MusclePharm Corp.*, the full quote IVC cites is:

We need not address whether plaintiffs are *ever* required to allege, at the pleading stage, that there are tests contradicting the nutrition panel that comply with the FDA's testing protocols. **We note, however, that plaintiffs are generally not expected to provide evidence in support of their claims at the pleading stage, see *Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011), nor are they required to plead the "probability" of their entitlement to relief,**

² If Plaintiff can show that this case indeed challenges only the name of the dietary supplement and not the stated "Supplement Facts," this testing regime may not apply at all. *See Amavizca v. Nutra Mfg., LLC*, No. 8:20-cv-01324-RGK-MAA, 2021 U.S. Dist. LEXIS 36009, at *1 (C.D. Cal. Jan. 27, 2021).

Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). In addition, FDCA preemption, like all federal preemption, is an affirmative defense. *Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1194 n.6 (9th Cir. 2018). **“Only when the plaintiff pleads itself out of court—that is, admits all the ingredients of an impenetrable defense—may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6).”** *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004); *see also Scott v. Kuhlmann*, 746 F.2d 1377, 1378 (9th Cir. 1984) (per curiam).

907 F.3d 595, 604 n.8 (9th Cir. 2018) (emphasis added). Even if it were controlling authority, it does not compel the Court to dismiss the claims at this stage. Plaintiff has not pleaded “all the ingredients of an impenetrable defense. *Id.* For example, she has not alleged that the tests are unreliable or inappropriate. *See* 21 C.F.R. §101.9(g) (“[C]omposites shall be analyzed by appropriate methods as given in the ‘Official Methods of Analysis of the AOAC International,’ or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.”). For these reasons, the Court denies IVC’s motion to dismiss based on preemption.

III.

Defendant IVC argues Plaintiff lacks standing to seek injunctive relief because she fails to allege future injury.

In order for a plaintiff to have Article III standing, she “must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Plaintiff has standing to pursue

injunctive or declaratory relief only if she is able “to establish a ‘real and immediate threat’ of injury.” *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 111–12 (1983)). Past injuries are insufficient to confer Article III standing “unless the plaintiff can demonstrate that she is likely to be harmed again in the future in a similar way.” *Id.*

Since Defendant Walgreen Co.’s motion to dismiss, the Second Circuit has addressed a plaintiff’s standing to assert claims for preliminary and permanent injunctive relief when the plaintiff has alleged that she would purchase the product in the future if the packaging were corrected:

[P]ast purchasers of a product...are not likely to encounter future harm of the kind that makes injunctive relief appropriate. In the first place, past purchasers are not bound to purchase a product again—meaning that once they become aware they have been deceived, that will often be the last time they will buy that item. Past purchasers do not have the sort of perpetual relationship with the producer of a consumer good that is typical of plaintiffs and defendants in Rule 23(b)(2) class actions. ...[T]here is no reason to believe that all, or even most, of the class members—having suffered the harm alleged—will choose to buy it in the future.

But even if they do purchase it again, there is no reason to believe that all, or even most, of the class members will incur a harm anew. Supposing that they have been deceived by the product’s packaging once, they will not again be under the illusion that the boxes of the newer pastas are filled in the same way as the boxes of the older pastas. Instead, next time they buy one of the newer pastas, they will be doing so with exactly the level of information that they claim they were owed from the beginning.

Berni v. Barilla S.p.A., 964 F.3d 141, 146-48 (2d Cir. 2020). This authority is controlling. Here, as in *Berni*, the Second Circuit’s determination precludes Plaintiff from injunctive relief. *Id.*

On that basis, the Court modifies its prior decision regarding Defendant Walgreen Co. and grants Walgreen’s motion to dismiss Plaintiff’s injunctive relief claim against it. *See Fort Knox Music Inc. v. Baptiste*, 257 F.3d 108, 110–11 (2d Cir. 2001) (Under FRCP 60(b), “nothing forbids the court to grant such relief *sua sponte*.”)

CONCLUSION

For the foregoing reasons, IVC’s motion to dismiss is GRANTED in part, and DENIED in part; and the Court *sua sponte* dismisses the claim for injunctive relief against Walgreen Co.

SO ORDERED.

/S/ Frederic Block
FREDERIC BLOCK
Senior United States District Judge

Brooklyn, New York
July 7, 2022